

Amendments to the Claims

This listing of claims will replace all prior versions, and listing, of claims in the application.

Listing of Claims:

1. (Currently Amended) A method for designing a patient-specific medical device for accessing a body cavity or lumen of a patient comprising:

(a) providing data relating to a three-dimensional geometric model of the cavity or lumen to a system comprising a device shape knowledge base which system performs an analysis using the provided data, the device shape knowledge base comprising a plurality of geometries for at least one segment of a device and rules for determining correspondence between a geometry of at least one segment and at least a portion of the model of the body cavity or lumen; and

(b) obtaining a recommendation from the system based on the analysis, the recommendation relating to the geometry of a device for placement into the cavity or lumen.

2. (Currently Amended) The method according to claim 1, ~~wherein the knowledge base is a device shape knowledge base comprising a plurality of geometries for at least one segment of a device and rules for determining correspondence between a geometry of at least one segment and at least a portion of the model of the body cavity or lumen and wherein the analysis uses the device shape knowledge bases to analyze the provided data.~~

3. (Previously Presented) The method according to claim 1, further comprising obtaining a volume image of the body cavity or lumen of the patient and generating the three-dimensional geometric model of the cavity or lumen from the volume image of the cavity or lumen.

4. (Original) The method according to claim 3, wherein the volume image is obtained from one or more of: an X-ray, Magnetic Resonance Imaging, Computer Tomography, rotational angiography, gadolinium enhanced MRA, and ultrasound.

5. (Original) The method according to claim 1, wherein the knowledge base comprises data relating to a physical property of the cavity or lumen.

6. (Original) The method according to claim 5, wherein the physical property is the elasticity of the cavity or lumen.

7. (Previously Presented) The method according to claim 1, further comprising displaying the recommendation on an interface of a user device connectable to a network.

8. (Previously Presented) The method according to claim 7, wherein the recommendation being displayed on the user device interface is in the form of a three-dimensional representation of the device.

9. (Previously Presented) The method according to claim 7, further comprising transmitting selectable options corresponding to design parameters of the device to the user device interface and displaying the selectable options thereon.

10. (Original) The method according to claim 9, wherein the selectable options are selected from the group consisting of: shape, material, flexibility, shape memory, stiffness, softness, pliability, stability, strength, contrast medium flow rate, length, size, and combinations thereof.

11. (Previously Presented) The method according to claim 9, further comprising selecting one or more of the selectable options and wherein the system simulates the design of the device based on the one or more selected options.

12. (Original) The method according to claim 1, wherein the device is selected from the group consisting of a catheter, a guidewire, a balloon, a balloon-inflating device, a coil, a stent, stent-graft, an endoscope, a laparoscope, a bronchoscope, a surgical device, a vascular occlusion device, an optical probe, and a drug delivery device.

13. (Original) The method according to claim 1 or 12, wherein the design of more than one device is simulated.

14. (Original) The method according to claim 13, wherein parameters selected for one of the devices is based on parameters of at least one of the other devices.

15. (Original) The method according to claim 1, wherein the medical device is designed to access a lumen which is a blood vessel.

16. (Canceled)

17. (Previously Presented) The method according to claim 1, wherein the device comprises multiple segments and wherein the method further includes selecting parameters of one or more of the multiple segments independently.

18. (Original) The method according to claim 17, wherein the device is selected from the group consisting of a catheter, a guidewire, a balloon, a balloon-inflating device, a coil, a

stent, stent-graft, an endoscope, a laparoscope, a bronchoscope, a surgical device, a vascular occlusion device, an optical probe, and a drug delivery device

19. (Original) The method according to claim 18, wherein at least one segment is selected from the group consisting of a tip, a rod element, a hook element and a hub.

20. (Original) The method according to claim 17, wherein at least two segments have varying material properties.

21. (Previously Presented) The method according to claim 1, wherein the system simulates a path representing at least a portion of the body cavity or lumen and wherein the method further comprises the system determining a best fit between the geometry of the device and the geometry of the path.

22. (Original) The method according to claim 1, wherein the method further comprises performing one or more feature operations to modify the recommended geometry.

23. (Original) The method according to claim 22, wherein the one or more feature operations are selected from the group consisting of shape sweeping, extruding, holing, braiding, edge rounding, and hub construction.

24. (Original) The method according to claim 1, further comprising performing a goal-driven search of the knowledge base to identify a device geometry which optimally corresponds to the model of the cavity or lumen.

25. (Original) The method according to claim 1, wherein the knowledge base includes clinical information relating to the patient.

26. (Original) The method according to claim 1, wherein the device geometry is determined using Finite Element Analysis.

27. (Original) The method according to claim 7, wherein in response to a query, the system displays a rule used for making the recommendation.

28. (Original) The method according to claim 1, wherein the patient has a pathology affecting the structure of the body cavity or lumen.

29. (Currently Amended) A system for designing a medical device for accessing a body cavity or lumen of a patient, comprising:

a device shape knowledge base comprising:

a plurality of geometries for at least one segment of a device; and

rules for determining correspondence between a geometry of at least one segment and at least a portion of a model of the body cavity or lumen, each rule comprising a statement associated with a certainty factor.

30. (Original) The system according to claim 29, further comprising a processor for receiving data relating to a three-dimensional geometric model of the cavity or lumen.

31. (Original) The system according to claim 29, wherein the data is obtained from a plurality of scanned images of the cavity or lumen.

32. (Original) The system according to claim 31, wherein the system is in communication with a scanning device for obtaining the scanned images.

33. (Original) The system according to claim 29, wherein the system further comprises a user device comprising an interface for interfacing with a user which is connectable to the knowledge base and the network.

34. (Original) The system according to claim 33, wherein the interface displays options for selecting one or more device parameters

35. (Original) The system according to claim 33, wherein the interface comprises fields for inputting clinical data relating to the patient.

36. (Original) The system according to claim 33, wherein the knowledge base transmits data relating to the one or more device segment geometries to the user interface upon receiving data relating to the geometry of the cavity or lumen.

37. (Original) The system according to claim 36, wherein the data relating to the one or more device segment geometries is in the form of a graphical representation of the one or more device segments.

38. (Original) The system according to claim 29, further comprising a device materials knowledge base comprising a plurality of data files relating to device materials and rules for determining suitability of a device material for at least one segment of the device.

39. (Original) The system according to claim 38, wherein the device materials knowledge base further comprises information relating to the elasticity of the portion of the body cavity or lumen.

40. (Original) The system according to claim 33, wherein selectable options corresponding to design parameters of the device are transmitted to, and displayed on, the interface of the user device based on the data relating to the geometry of at least a portion of the cavity or lumen.

41. (Original) The system according to claim 40, wherein the selectable options are selected from one or more of the group consisting of: shape, material, flexibility, shape memory, stiffness, softness, pliability, stability, strength, contrast medium maximum flow rate, length, size.

42. (Original) The system according to claim 40, wherein when one or more of the selectable options are selected, the system simulates the design of the device based on the selected options.

43. (Original) The system according to claim 38, wherein the system simulates a path representing at least a portion of the body cavity or lumen and determines best fit between the geometry of the device and the geometry of the path.

44. (Original) The system according to claim 33, wherein one or more feature operations are displayed on the interface and wherein selecting a feature operation modifies the shape of at least a segment of the device.

45. (Original) The system according to claim 44, wherein the one or more feature operations are selected from the group consisting of shape sweeping, extruding, holing, braiding, edge rounding, and hub construction.

46. (Original) The system according to claim 29, further comprising an expert system for identifying relationships between data in the knowledge base and data relating to the images.

47. (Original) The system according to claim 29, further comprising a data file comprising clinical information relating to the patient.

48. (Original) The system according to claim 29, further comprising a Finite Element Analysis engine.

49. (Currently Amended) A software suite for design of a medical device for accessing a body cavity or lumen comprising:

a first component for storing a device shape knowledge base, the knowledge base comprising a plurality of geometries for at least one segment of the device and rules for determining correspondence between the geometry of the at least one segment and at least a portion of a geometric model of the body cavity or lumen, each rule comprising a statement associated with a certainty factor; and

a second component comprising an executing function for executing one or more programs for determining whether one or more of the geometries of the at least one segment corresponds to the geometric model of at least a portion of the body cavity or lumen based on the rules for determining correspondence.

50. (Original) The software suite of claim 49, further comprising a second component for interfacing with a user device; wherein the second component provides a retrieval function for retrieving data relating to a geometric model of at least a portion of the body cavity or lumen and a transmitting function for transmitting the data to the knowledge base.

51. (Currently Amended) A method for designing a medical device for accessing a body cavity or lumen of a patient comprising:

(A) providing data relating to a three-dimensional geometric model of the cavity or lumen to a system comprising a knowledge base which system performs an analysis using the provided data;

(B) obtaining a recommendation from the system based on the analysis, the recommendation relating to the geometry of a device for placement into the cavity or lumen; wherein the knowledge base includes:

(a) a diagnostic and pathological information knowledge base, where the provided data/information for the patient is inputted into the diagnostic and pathological information knowledge base,

(b) a device shape knowledge base, and

(c) a device physical material knowledge base;

(C) analyzing the provided data and determining the physical properties of the body cavity or lumen of the patient; and

wherein said obtaining a recommendation includes:

(1) determining one or more appropriate shapes and designs of the device for placement in the body cavity/ lumen using the determined physical properties of the body cavity or lumen of the patient and using facts and rules of the device shape knowledge base, and

(2) determining one or more physical properties and/ or characteristics of the device for placement in the body cavity/ lumen using facts and rules of mechanics and physical properties of the body cavity/ lumen being targeted of the device physical material knowledge base.

52. (Currently Amended) A method for designing a medical device for accessing a body cavity or lumen of a patient comprising:

(A) providing data relating to a three-dimensional geometric model of the cavity or lumen to a system comprising a knowledge base which system performs an analysis using the provided data;

(B) obtaining a recommendation from the system based on the analysis, the recommendation relating to the geometry of a device for placement into the cavity or lumen; and wherein the knowledge base includes:

(a) a diagnostic and pathological information knowledge base, where the provided data/information for the patient is inputted into the patient specific diagnostic and pathological information knowledge base,

(b) a device shape knowledge base; and

(C) analyzing the provided data and determining the physical properties of the body cavity or lumen of the patient; and

wherein said obtaining a recommendation includes determining the appropriate shape and design of the device for placement in the body cavity/ lumen using the determined physical properties of the body cavity or lumen of the patient and using facts and rules of the device shape knowledge base.

53. (Currently Amended) A method for designing a medical device for accessing a body cavity or lumen of a patient comprising:

(A) providing data relating to a three-dimensional geometric model of the cavity or lumen to a system comprising a knowledge base which system performs an analysis using the provided data;

(B) obtaining a recommendation from the system based on the analysis, the recommendation relating to the geometry of a device for placement into the cavity or lumen;

wherein the knowledge base includes:

- (a) a diagnostic and pathological information knowledge base, where the provided data/ information for the patient is inputted into the patient specific diagnostic and pathological information knowledge base,
- (b) a device physical material knowledge base;
- (C) analyzing the provided data and determining ~~the~~ physical properties of the body cavity or lumen of the patient; and

wherein said obtaining a recommendation includes determining physical properties and/ or characteristics of the device for placement in the body cavity/ lumen using facts and rules of mechanics and physical properties of the body cavity/ lumen being targeted of the device physical material knowledge base.

54. (Currently Amended) The method of any ~~one~~ of claims 51-53, further comprising:
generating a geometric model of the body cavity or lumen from the provided data; and
wherein said determining includes determining the appropriate shape and design of the device for placement in the body cavity/ lumen using the generated geometric model of the body cavity or lumen of the patient and using facts and rules of the device shape knowledge base.

55. (Previously Presented) The method of claim 1, further comprising:
generating a geometric model of the body cavity or lumen from the provided data; and
wherein said obtaining a recommendation from the system further includes obtaining a recommendation of a geometry, topology and physical properties of a device for placement into the cavity or lumen using the generated geometric model.

56. (Previously Presented) The method of claim 1, further comprising:
generating a geometric model of the body cavity or lumen from the provided data; and
wherein said obtaining a recommendation from the system further includes obtaining one or more recommendations of a geometry, topology and physical properties for one or more devices for placement into the cavity or lumen using the generated geometric model.

57. (Currently Amended) An application program for execution on a processor, the software program being arranged so as to provide an output of one or more designs for a medical device that accesses a body cavity or lumen of a patient, said applications program including one or more knowledge bases and a processing part:

wherein said one or more knowledge bases includes:

(a) a diagnostic and pathological information knowledge base, where provided data/information for the patient is inputted into the diagnostic and pathological information knowledge base,

(b) a device shape knowledge base including facts and rules, and
wherein the processing part includes instructions and criteria for:

analyzing the data/ information being provided for the patient and determining the physical properties of the body cavity or lumen of the patient;

determining one or more appropriate shapes and designs of the device for placement in the body cavity/ lumen using the determined physical properties of the body cavity or lumen of the patient and using the facts and rules of the device shape knowledge base, and

providing an output of the determined one or more appropriate shapes and designs.

58. (Previously Presented) The application program of claim 57, wherein:
wherein said one or more knowledge bases includes:

(c) a device physical material knowledge base including facts and rules;
wherein the processing part includes instructions and criteria for:

determining one or more physical properties and/ or characteristics of the device for placement in the body cavity/ lumen using the facts and rules of mechanics and physical properties of the body cavity/ lumen being targeted of the device physical material knowledge base; and

wherein the instructions and criteria for providing an output further includes instructions and criteria for providing an output of the determined one or more physical properties and/ or characteristics.

59. (Currently Amended) The application program of any one of claims 57-58, wherein:
the instructions and criteria for said analyzing the data/ information being provided for the patient and determining the physical properties of the body cavity or lumen of the patient includes instructions and criteria for generating a geometric model of the body cavity or lumen from the provided data and

wherein the instructions and criteria for determining one or more appropriate shapes and designs of the device for placement in the body cavity/ lumen includes instructions and criteria for determining one or more appropriate shapes and designs of the device using the generated geometric model.

60. (Previously Presented) The application program of any of claim 57, wherein:
the device is comprised of a plurality of segments;
wherein the instructions and criteria for determining one or more appropriate shapes and designs of the device for placement in the body cavity/ lumen includes instructions and criteria for determining one or more appropriate shapes and designs for each segment of the device.

61. (Currently Amended) The application program of any one of claims 57-58, wherein:
the device is comprised of a plurality of segments;
the instructions and criteria for said analyzing the data/ information being provided for the patient and determining the physical properties of the body cavity or lumen of the patient includes instructions and criteria for generating a geometric model of the body cavity or lumen from the provided data and

wherein the instructions and criteria for determining one or more appropriate shapes and designs of the device for placement in the body cavity/ lumen includes instructions and criteria for determining one or more appropriate shapes and designs of each segment of the device using the generated geometric model.

62. (Previously Presented) The application program of claim 58, wherein:
the device is comprised of a plurality of segments;
wherein the instructions and criteria for determining one or more physical properties and/
or characteristics of the device for placement in the body cavity/ lumen includes instructions and
criteria for determining one or more physical properties and/ or characteristics of each segment of
the device using the facts and rules of mechanics and physical properties of the body cavity/
lumen being targeted of the device physical material knowledge base.

63. (Previously Presented) The application program of claim 57, wherein the
instructions and criteria of the processing part further includes instructions and criteria so as to
create an inference engine for carrying out said determining one or more appropriate shapes and
designs.

64. (Previously Presented) The application program of claim 58, wherein the
instructions and criteria of the processing part further includes instructions and criteria so as to
create an inference engine for carrying out said determining one or more one or more physical
properties and/ or characteristics of the device.

65. (Previously Presented) The application program of claim 57, wherein the
instructions and criteria of the processing part further includes;
instructions and criteria for user overwriting of one or more parameters as automatically
determined by the processing part; and
for causing the respective one or more of the knowledge bases to learn new parameters
associated with a new design or physical property from such overwriting.

66. (Previously Presented) The application program of claim 57, wherein the processing part further includes instruction and criteria for:

emulating a device having one of the outputted determined one or more appropriate shapes and designs;

simulating navigation of at least a portion of the device from the entry point of a patient's body to the body cavity or lumen; and

determining changes to the design and proving an output of such changes based on said simulating and the facts and rules of the knowledge data bases.